United States Department of Agriculture
Animal and Plant Health Inspection Service

201919 GLADUE insp_id

Inspection Report

RHODE ISLAND HOSPITAL

Customer ID: **266**
Certificate: **15-R-0002**
Site: 001
(b)(2)High, (b)(7)f

MIDDLE HOUSE 4TH AND 5TH

PROVIDENCE, RI 02903

Type: ROUTINE INSPECTION
Date: Jun-06-2008

This was a focused inspection based on the non-compliant items that were identified during the last inspection. Registrant has successfully addressed and has implemented corrective actions for the non-compliant items identified at the time of the last inspection.

Prepared By: PAULA S GLADUE, V M D USDA, APHIS, Animal Care — **Date:** Jun-06-2008
Title: VETERINARY MEDICAL OFFICER Inspector 1054

Received By: (b)(6),(b)(7)(c) — **Date:** Jun-06-2008
Title:

Inspection Report

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MIDDLE HOUSE 4TH AND 5TH

PROVIDENCE, RI 02903

Customer ID: **266**
Certificate: **15-R-0002**
Site: 001
(b)(7)f, (b)(2)High
Type: --RESCINDED--
Date: May-08-2008

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (viii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

1. Review of Protocol #0013-08:

a. It was learned during the inspection that one of the individuals who was providing animal care and conducting procedures on the study animals had not been listed on the protocol as one of the personnel to be involved in the project.

All personnel conducting procedures on animals must be named on a proposal for animal use in order for the IACUC to determined that the personnel are qualified and trained in those procedures.

The IACUC needs to address this issue identified for this proposal. Correct immediately.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) -"A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals."

1. Review of Protocol #0013-08 and Medical Records of GP #1 through 24:

a. The records of six GP (#7, 8, 21, 22, 23, 24) indicate that the substances Calcein and BrdU were administered to the GP by injection. There is no description of the injection of these substances included in the approved protocol.

b. The records of eighteen GP (#1 through 6, #9 through 20) indicate that the antibiotic Cephazolin was injected at

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the time of surgery. There is no description of the injection of Cephazolin in the approved protocol.

c. The protocol states on pg 18 that size 4-0 Nylon suture will be used to close the surgical incision. It was noted during the inspection that the size and type of suture used to close the incisions of the GPs that had undergone surgery was different than what was described in the approved protocol.

d. It is not clear from the description of the schedule of administration of analgesics whether Buprenorphine is given only on the day of surgery or also on the first post-operative day.

A proposal for animal use must contain a complete description of the proposed animal use. The IACUC needs to address the items identified for this protocol. Correct by 6/1/08.

2.32 (a)

PERSONNEL QUALIFICATIONS.

2.32 (a) -"It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties."

1. The Non-compliant items identified on this inspection report under Sections 2.31 (d) (1) (viii), 2.31 (e) (3), 2.33 (b) (3), and 2.33 (b) (5) pertaining to Protocol #0013-08 indicate laboratory personnel's lack of familiarity with both the details of the approved protocol and currently established veterinary medical and nursing procedures. This lack of familiarity has the potential to negatively affect the welfare of animals.

All personnel involved in animal care, treatment, and use must be adequately trained and qualified to perform the duties described in the protocol. Inadequate training in any aspect of animal care and use can result in harm to the animals. The research facility needs to address this issue. Correct immediately.

2.33 (b) (3) **DIRECT NCI**

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (3) - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian."

1. DIRECT ITEM: At the time of the inspection at approximately 11 AM on 5/8/08, the APHIS inspector noted that GP #15 used under Protocol #0013-08 was depressed, thin, had sunken eyes, a ruffled hair coat, a red and swollen surgical incision on the right rear leg, and was reluctant to move. According to the animal's medical record, the investigator had observed the animal to be sedentary, undernourished, and having small eyes on 5/7/08. The PI administered the antibiotic Cephazolin but did not contact the clinical veterinarian regarding the animal's condition as was described in the approved protocol under post-operative monitoring.

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The clinical veterinarian was first made aware of the condition of this animal at the time of the inspection on 5/8/08. The PI was immediately contacted by the clinical veterinarian and instructed to euthanize the GP.

A mechanism of direct and frequent communication by laboratory personnel to the veterinarian regarding problems of animal health and behavior is important to protect the health and well-being of the animals. The facility needs ensure that all personnel responsible for the daily observations of research animals provide any information concerning any problem of animal health to the veterinarian for evaluation. Correct from this date forward.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. Review of Protocol #0013-08 and the Medical Records of GP #1 - 6 and #9 - 20:

a. The protocol states that the GP will monitored twice a day for one week post-operatively. There was no documentation available that the post-operative monitoring schedule was followed as described in the protocol.

b. The protocol states that any GP having surgery in the morning will have a second dose of the analgesic Buprenorphine administered in the evening. It could not be determined from the information available whether the schedule of administration of analgesic was followed.

c. GP #15 received an injection of the antibiotic Cephazolin by the PI on 5/7/08 without consulting the clinical veterinarian. The protocol states that any possible wound infections will be brought to the attention of the veterinarian for consultation.

d. The medical records of the GP contained insufficient information to determine that the procedures performed on the animals had been conducted as described in the approved protocol.

Research animals should receive the prescribed pre and post procedural care as specified in the IACUC approved proposal for animal use to maintain the health of the animals and ensure that discomfort and pain to the animals will be limited. The IACUC and AV need to address the items identified for this protocol. Correct immediately.

2.36 (b) (7)

ANNUAL REPORT.

2.36 (b) (7) - "The annual report shall: (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely

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affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report."

1. The Annual Report that was submitted by the research facility to USDA for FY 2007 did not include 8 Rabbits that were used under Protocol #0182-06 during FY 2007. The 8 Rabbits were considered likely to have experienced unrelieved pain and/or distress as a result of the failure of the investigator to administer post-operative analgesia as per the approved protocol.

The research facility needs to submit a corrected Annual Report for FY 2007 to the Eastern Regional Office that reports the 8 Rabbits in the correct pain category and attach an explanation of the incident. Correct by 7/1/08.

NOTE - This inspection was conducted on 5/8/08 and 5/9/08 with the exit interview on 5/9/08.

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the time of surgery. There is no description of the injection of Cephazolin in the approved protocol.

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NOTE - This inspection was conducted on 5/8/08 and 5/9/08 with the exit interview on 5/9/08.

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NOTE - This is an amended version of the inspection report that was delivered to the facility at the 5/9/08 exit interview.

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